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Actavis to Pay Up to \$13 Million to Resolve Digitek Lawsuits

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By Jef Feeley and Sophia Pearson

Dec. 7 (Bloomberg) -- Actavis Group hf, an Icelandic maker of generic drugs, will pay as much as \$13 million to resolve claims that it failed to warn consumers that its Digitek heart pill was defective.

Actavis agreed to create a \$10 million fund as a base and add as much as \$3 million more if 98 percent of people with Digitek claims participate in the settlement, Gerard Farrell, a U.S.-based spokesman for the closely held drugmaker, said today in an e-mailed statement. Enough consumers already have taken part to push the settlement amount to \$12 million, according to three people with direct knowledge of the accord.

"Only those individuals who are able to demonstrate actual harm will receive compensation," Farrell said.

Actavis officials agreed in September to set up the settlement fund to resolve as many as 3,000 lawsuits alleging the Reykjavik-based company misled consumers about Digitek, used to treat heart failure and abnormal heart rhythms, the people said. They spoke on the condition of anonymity because they weren't authorized to speak publicly about the accord.

The settlement, which also covers suits against generic drug maker Mylan Inc. over its marketing of Digitek, provides an average recovery of at least \$4,000 each for consumers who took the defective drugs, the people said. Actavis and Mylan recalled Digitek in 2008 after finding some batches of the pills may have had double the amount of chemical they were supposed to contain.

'Nuisance-Value'

"That is not a lot of money, especially when the allegations are that users were seriously harmed by the defective version of this drug," said Carl Tobias, a law professor at the University of Richmond in Virginia who teaches classes about mass-tort cases. "These amount to nuisance-value settlements."

Michael Laffin, a Mylan spokesman, didn't return a phone call and e-mails today seeking comment on the settlement.

Digitek is a form of digitalis, a chemical derived from the foxglove plant that has been used as a heart medicine since the 18th century. The medication is sold generically as digoxin and excess dosing can cause dizziness, low blood pressure and death, U.S. Food and Drug Administration officials said at the time of the recall.

In April 2008, Actavis recalled Digitek after finding that some of the pills the company produced were double the appropriate thickness and contained twice the approved level of digitalis. The company said it also had received almost a dozen reports of adverse side effects tied to the drug.

Federal Suit

Federal officials sued Actavis in November 2008 for failing to comply with FDA standards in three U.S. plants, including one that produced Digitek. That case was resolved by an agreement between the company and government lawyers a month after it was filed, Farrell said today.

A majority of the suits over the heart drug have been consolidated before U.S. District Judge Joseph Goodwin in Charleston, West Virginia, who is overseeing pre-trial evidence-gathering in the cases.

Lawyers for consumers alleged the production problems at Actavis's New Jersey plants caused some of the Digitek pills to be defectively produced with a double dosage. Actavis made the drug and Mylan, based in Canonsburg, Pennsylvania, marketed it in the U.S.

Some plaintiffs' lawyers soured on the cases after struggling to find any of the double-dosage pills on the market or in their clients' medicine cabinets, the people familiar with the settlement said. The companies still were willing to pay to settle the cases to hold down litigation costs, Tobias said.

"They can get the majority of these cases resolved and avoid spending a ton on legal fees defending themselves," the law professor said.

Mylan Dismissed

Mylan "will not contribute monetarily to the settlement, but it will be dismissed" from any settled cases, company officials said in an Oct. 28 regulatory filing.

Goodwin on Nov. 8 approved Actavis's motion to set up a Digitek settlement fund. The company had until Dec. 1 to withdraw if too many consumers opted out of the settlement process, according to the people familiar with the accord. So far, more than 20 consumers who sued Actavis and Mylan over Digitek decided not to join the settlement and pressed ahead with their claims, the people said.

Billionaire Icelandic investor Bjorgolfur Thor Bjorgolfsson and his company Novator acquired Actavis and took it private in 2008. In June, the company named Claudio Albrecht, the former chief executive officer of Ratiopharm GmbH, as its new CEO.

The case is In re Digitek Products Liability Litigation, 2:08-md-1968, U.S. District Court, Southern District of West Virginia (Charleston).

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